



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,954	07/12/2001	Michael E. Garst	17095CIPCON(AP)	3028

7590
ALLERGAN, INC.
Carlos A. Fisher-T2-7H
2525 Dupont Drive
Irvine, CA 92612

09/03/2008

EXAMINER

FAY, ZOHREH A

ART UNIT	PAPER NUMBER
----------	--------------

1612

MAIL DATE	DELIVERY MODE
-----------	---------------

09/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/903,954
Filing Date: July 12, 2001
Appellant(s): GARST, MICHAEL E.

Carlos Fisher
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 25, 2007 appealing from the Office action mailed November 2, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,877,211

Woodward

3-1999

Yavitz, "LASIK surgery shows brimonidine provides neuroprotective effect", Ocular Surg News 1999 Sep 1; 17(17):28

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21-25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yavitz in view of Woodward (US 5,877,211).

Yavitz teaches the use of the claimed compound, brimonidine, being an alpha adrenergic agonist, having neuroprotective effect during ophthalmic surgery. See the entire article. Woodward teaches the neuroprotective effect of prostaglandin receptor agonists in the ophthalmic field. See the abstract and claims. Woodward also in general teaches that it has been long known that glaucoma causes damage to optic nerve. (see column 1, lines 53-59). Woodward in column 3, lines 39-59 teaches the effect of prostaglandins, such as 11-pivaloyl PGF₂ in treating glaucoma. The primary reference differs from the claimed invention in the presence of a prostaglandin receptor

Art Unit: 1612

agonist. It would have been obvious to a person skilled in the art to add a prostaglandin to the composition of Yavitz, considering that Woodward teaches the neuroprotective effect of prostaglandin receptor agonists in ophthalmic field.

One skilled in the art would have been motivated to combine the teachings of the above reference, since one relates to the use of the claimed alpha-adrenergic agent having neuroprotective activity in the ophthalmic field and the other relates to the use of prostaglandins having neuroprotective effect in the ophthalmic field. It is generally prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea of combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of two components having neuroprotective activity in the ophthalmic field. See *In re Kerkhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

(10) Response to Argument

Appellant's arguments and remarks have been carefully considered, but are not deemed to be persuasive. Appellant in his remarks argues that the data in Yavitz reference suggests that the brimonidine may be neuroprotective. The arguments are not well taken. Appellant is reminded that obviousness does require absolute predictability. Appellant also argues that Woodward discloses the ability of certain agonists of prostaglandins EP2 receptor to protect cultured rat hippocampal neurons in cell culture against challenge with excitatory amino acid glutamate. Appellant states

Art Unit: 1612

that Woodward concludes that PGF2a and PGF2a-OH are inactive in this assay, thereby indicating that this protective result is a PGE2 mediated receptor effect. It appears that appellant has picked the teachings of a portion of the reference and has not given any weight to the teachings of Woodward as a whole.

The question of obviousness is resolved on the basis underlying factual determinations including: (1) the scope and content of prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art and (4) secondary consideration of non-obviousness if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). In *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, (2007), the Supreme Court reiterated "the need for caution in granting a patent based on the combination of elements found in prior art", and counseled that "the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results". The principle issue raised in this case, then, is whether the combination of an alpha adrenergic agent, such as brimonidine and a prostaglandin receptor agonist would have been obvious at the time of the invention, given the scope and content of the prior art, the level of ordinary skill in the art and the difference between the claimed invention and the prior art. It is the examiner's position that it would have been obvious to combine a prostaglandin receptor agonist and an alpha adrenergic agonist and use the combination for the protection of ophthalmic nerve, given the recognition by the prior art, that brimonidine, an alpha adrenergic agonist has been used as a neuroprotective agent, and the recognition that glaucoma causes damage to optic nerve (Woodward, col. 1, lines 54-58), and the claimed

Art Unit: 1612

prostaglandins have been used for the treatment of glaucoma (Woodward, col. 3, lines 39-59). Furthermore, Woodward teaches the neuroprotective effect of certain prostaglandin receptor agonists, within the scope of what is claimed. Appellant arguments regarding the lack of neuroprotective effect of PGF_{2a} is not considered to be persuasive, considering that the prior art teaching is related to one experimental study, with one type of cytotoxic agent. In conclusion: It is generally prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea of combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of two components having neuroprotective activity in the ophthalmic field. See *In re Kerkhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Zohreh A Fay/

Primary Examiner, Art Unit 1612

Conferees:

Art Unit: 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612

/Johan R. Richter, Ph.D., Esq./

Supervisory Patent Examiner, Art Unit 1616